SIEMENS

May 13, 2005

U.S. Food and Drug Administration
Division of Dockets Management
5630 Fishers Lane, Room 1061
Rockville, MD 20852

1045 5 MAY 17 A9:19

RE: Docket No. 2004N – 0527

Dear Sir or Madame:

Siemens Medical Solutions USA, Inc. would like to offer comment on the U.S. Food & Drug Administration's proposed amendment to the existing Medical Device Reporting (MDR) regulations. Siemens is a global manufacturer and importer of medical devices for the X-Ray Imaging, Computed Tomography, Radiation Therapy, Nuclear Medicine Imaging, Diagnostic Ultrasound, and Magnetic Resonance Imaging Industries.

Siemens recommends that the language regarding who is qualified to make a medical judgment be revised. The proposed amendment lists specific individuals who are qualified to make reporting judgments: physicians, nurses, risk managers and biomedical engineers. The regulation in its current form merely lists these occupations as examples of people qualified to make a medical judgment. Siemens feels that other individuals with adequate knowledge, education, and/or training about a general product and its intended use are also qualified to make reasonable conclusions regarding the reportability of an event. This could encompass a number of individuals employed in various occupations by medical device manufacturers. Siemens believes a device manufacturer may have extensive knowledge regarding the safety relevance of a product-related incident, due to their familiarity with the device and its intended use, as well as their knowledge regarding the cause and prevalence of an incident. Furthermore, a healthcare professional may not necessarily be well versed in the regulatory requirements for adverse event reporting.

Siemens believes that FDA's proposed change would limit device manufacturers' ability to use their valuable internal experts when making MDR judgments. Furthermore, this change in the scope of the regulation may result in incomplete MDR reports, or unreported incidents due to insufficient information.

Siemens recommends that FDA revise the proposed rule to the following:

"If you are a user facility, importer, or manufacturer, you do not have to report an adverse event if you have information that would lead a qualified person (e.g., a physician, nurse, risk manager, or biomedical engineer) to make a reasonable conclusion that a device did not cause or contribute to a death or serious injury, or that a malfunction would not be likely to cause or contribute to a death or serious injury if it were to recur.

2004N-0527 C5

Siemens Medical Solutions USA, Inc.

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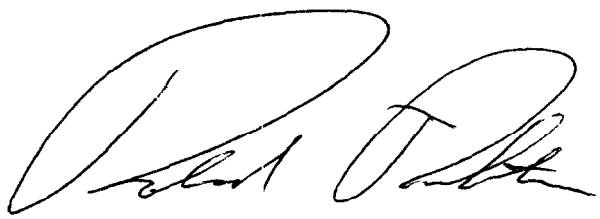
Thank you for the opportunity to share Siemens' views on this important matter. If you have any questions, please contact me by phone at 610-448-1777 or by e-mail at richter.roland@siemens.com.

Sincerely,



Roland Richter
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